No. 2016-1814

IN THE
United States Court of Appeals
FOR THE FEDERAL CIRCUIT

SOFT GEL TECHNOLOGIES, INC.,
Appellant,

v.

JARROW FORMULAS, INC.,
Appellee.

Appeal from the Patent Trial and Appeal Board of the
United States Patent and Trademark Office
In Re-Examination 95/002,396

CORRECTED BRIEF OF APPELLEE JARROW FORMULAS, INC.

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CERTIFICATE OF INTEREST

Counsel for Appellee, Jarrow Formulas, Inc., certifies the following in accordance with Federal Circuit Rule 47.4:

1. The full names of every party or amicus represented by the undersigned are:

   Jarrow Formulas, Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by the undersigned is:

   None

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by the undersigned are:

   None

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court (and who have not or will not enter an appearance in this case) are:

   None.

Dated: November 2, 2016

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1. Citations to the Appendix are in the form Appx123, where page "123" of the Appendix is the cited page. When citing to patent documents, column and line numbers for given pages are cited as 1:7-10, where column 1, lines 7-10 are cited.

2. "'072 patent" refers to U.S. Patent No. 8,124,072.

3. "'583 patent" refers to U.S. Patent No. 8,105,583.

4. "ACP" refers to the Action Closing Prosecution in Reexamination Control No. 95/002,396 regarding the '072 patent, mailed on July 8, 2013.

5. "Brief" refers to the brief of Appellant Soft Gel Technologies, Inc., Docket No. 19.

6. "Board" or "PTAB" refers to The Patent Trial and Appeal Board of the United States Patent & Trademark Office.

7. "Coenzyme Q10", "CoQ10", "Q-10" or "ubiquinone" refers to ubiquinone.

8. "Davidson" refers to prior art U.S. Patent Publication No. US2004/0001874, published on January 1, 2004.

9. "DSC" refers to Differential Scanning Calorimetry.

10. Dr. Nazzal refers to Sami Nazzal, the author of Nazzal (below).

11. "Duetz" refers to the prior art reference Duetz et al., "Biotransformation of D-Limonene to (+) trans-Carveol by Toluene-Grown *Rhodococcus opacus* PWD4 Cells," Applied and Environmental Microbiology (2001).

12. "Fenaroli" refers to the prior art reference Fenaroli, G., "Fenaroli's Handbook of Flavor Ingredients," CRC Press (1975).

13. "IARC" refers to the prior art reference "IARC Monographs on the Evaluation of Carcinogenic Risks to Humans," pages 135-37 (1993).

14. "Jarrow" refers to Appellee Jarrow Formulas, Inc.

15. "Khan" or "Khan '786" refers to the prior art reference U.S. Patent No. 7,588,786 B2 to Khan et al.

16. "Khan 2004" refers to the study published as A. Palamakula, M. Soliman, I.K. Reddy and M.A. Khan, "Preparation and In Vitro Characterization of Self-Nanoemulsified Drug Delivery Systems of Coenzyme Q-10 Using Chiral Essential Oil Components," Pharmaceutical Technology, October 2004.

17. "Lota" refers to the prior art reference Lota et al., "Volatile Components of Peel and Leaf Oils of Lemon and Lime Species," Journal of Agriculture and Food Chemistry (2002).

18. "Mondello" refers to the prior art reference Mondello et al., "Multidimensional Capillary GC-GC for the Analysis of Real Complex Samples,

3. Enantiomeric Distribution of Monoterpene Hydrocarbons and Monoterpene Alcohols of Mandarin Oils," Journal of Agriculture and Food Chemistry (1998).

19. "Motoyama" refers to the prior art reference Motoyama et al., Patent Application Laid-Open Disclosure S57-42616, published Mar. 10, 1982.

20. "Nazzal" refers to the prior art reference Nazzal, Sami Mahmoud, "Eutectic-Based Self-Nanoemulsified Drug Delivery Systems for Solid Oral Dosage Forms," Graduate Dissertation dated August 2002, pages 1-289.

21. "RAN" refers to the Right of Appeal Notice in Reexamination Control No. 95/002,396 regarding the '072 patent, mailed on April 30, 2014.

22. "SNEDDS" refers to a self-nanoemulsified drug delivery system.

23. "Soft Gel" refers to Appellant Soft Gel Technologies, Inc.

24. "Steele" refers to prior art European patent application number EP 0 888 774 A2, published January 7, 1999.

25. "Steuer" refers to the prior art reference Steuer et al., "Classification and Analysis of Citrus Oils by NIR Spectroscopy," Food Chemistry (2001).

STATEMENT OF THE ISSUES

1. Whether substantial evidence supports the factual findings that each of Khan and Nazzal anticipates claims 1-3, 6-10, 14-20 and 24.

2. Whether substantial evidence supports the Board's factual findings that (a) Motoyama taught that CoQ10 will dissolve in carvone in a 50/50 ratio of CoQ10/carvone, and that carvone containing oils, such as peppermint oil and spearmint oil, also readily dissolve CoQ10, (b) Khan/Nazzal taught that peppermint oil, spearmint oil and lemon oil are about equally effective in melting and thereby solubilizing CoQ10, (c) Fenaroli, Duetz, Mondello and IARC each taught that the main constituent of lemon oil is d-limonene, and (d) Nazzal taught that limonene and carvone can be evaluated for their potency in melting and thereby solubilizing CoQ10.

3. Whether the Board's legal conclusion of obviousness was correct where Nazzal taught that limonene can be evaluated for its potency in melting and thereby solubilizing CoQ10 and Soft Gel's expert admitted that it would have been obvious to try lemon oil in the composition described in Motoyama.

4. Whether clarification of the Board's findings in a related case require remand where the Board's findings in this case are supported by substantial evidence and the Board's clarification in the related case did not change the Board's obviousness determination in that case.

STATEMENT OF RELATED CASES

This is an appeal from a final decision by the Board affirming the Examiner's rejection of claims 1-24 of the '072 patent in an *inter partes* reexamination filed by Jarrow. The reexamination Control Number is 95/002,396.

This appeal is related to Case 16-1815 pending before this Court, which is an appeal from a decision by the Board affirming the rejection of claims 1, 2, 4, 6-10, 12-13 and 15-17 of U.S. Patent No. 8,105,583 in an *inter partes* reexamination filed by Jarrow. The reexamination Control Number is 95/002,405.

This appeal is also related to Case 17-1051 pending before this Court, which is an appeal from a decision by the Board affirming the rejection of all of the claims of U.S. Patent No. 8,147,826 in an *inter partes* reexamination filed by Jarrow. The reexamination Control Number is 95/002,411.

In its Statement of Related Cases, Soft Gel improperly cites two concluded district court cases involving one of the prior art references cited by the Board, Khan. Those cases are not related cases under Federal Circuit Rule 47.5(b). Those cases are not pending, do not directly affect this case and are not directly affected by this case.

STATEMENT OF THE CASE

In accordance with Federal Circuit Rule 28(b), Jarrow provides this Statement of the Case limited to areas of disagreement with Appellant's statement.

I. Summary of Claimed Subject Matter

The amended claims of the '072 patent recite, in pertinent part, CoQ10 "***solubilized*** in a sufficient quantity of d-limonene suitable to solubilize said coenzyme Q-10 to form a solution, wherein the amount of coenzyme Q-10 in said solution is about 15 percent up to about 60 percent coenzyme Q-10 by weight." (Appx957-959 (emphasis added).) Nazzal and Khan taught that CoQ10 is difficult to dissolve in water and fixed oils and used the melting point reduction method in essential oils, such as lemon oil, peppermint oil and spearmint oil, to melt and thereby solubilize the CoQ10. (Appx493 at 2:46-51, Appx495 at 6:57-60.) It was known in the art that d-limonene is the main constituent of lemon oil. (Appx1106, Appx1624, Appx1987.)

II. The Prior Art

Nazzal and Khan teach binary mixtures of CoQ10 solubilized in lemon oil, and d-limonene is the main constituent of lemon oil. (Appx495 at 6:27-40, Appx1106, Appx1624, Appx1987.) Nazzal and Khan also disclose compositions referred to as "SNEDDS". The SNEDDS comprise oily mixtures of CoQ10 solubilized in an essential oil with surfactants, that are filled into soft or hard gelatin capsules. (Appx494 at 4:48-54.) The SNEDDS are not emulsions, but

rather only form emulsions when introduced into an aqueous medium, such as the gut. (Appx493 at 2:52-55.)

III. The Federal Court Litigation Involving Khan

The federal court action involving Khan has no bearing on the issues in this case. The issues litigated in the federal court action were claim construction, infringement and validity of Khan. (Appx696-723.) The '072 patent, on the other hand, was not at issue in the federal court action, and the court did not in any way address the construction or validity of its claims. Thus, the issues litigated in the two proceedings are entirely different, and the federal court judgment on infringement of Khan has no bearing on the issues in this case.

SUMMARY OF THE ARGUMENT

Substantial evidence supports the Board's finding that Khan and Nazzal each anticipate claims 1-2, 6-10, 14-20 and 24 of the '072 patent, and therefore this finding should be affirmed for the following reasons:

1. The record evidence establishes that (i) Khan/Nazzal demonstrated that increasing amounts of lemon oil in mixtures of CoQ10 and lemon oil progressively reduced the melting point of the CoQ10; (ii) there was a sufficient quantity of lemon oil in Khan/Nazzal's mixtures to reduce the melting point of the CoQ10 to at or below body temperature; (iii) upon melting, the CoQ10 transitioned from solid crystals to a liquid; (iv) the liquefied CoQ10 was thereby solubilized in the lemon oil; (v) d-limonene is the main constituent of lemon oil; (vi) the CoQ10 was necessarily solubilized in the d-limonene of the lemon oil; and (vii) since the CoQ10 was solubilized in the d-limonene of the lemon oil, the lemon oil necessarily had a sufficient quantity of d-limonene suitable to solubilize it, as claimed.

2. The record evidence presented sufficient factual findings to reasonably infer that Khan/Nazzal's solution containing CoQ10 and d-limonene was the same as the claimed solution. The burden of production, therefore, properly shifted to Soft Gel to show that the solutions were not the same. Soft Gel argues that the "mechanism" of its claimed composition is different, and that the

CoQ10 in the claimed composition is purportedly solubilized without melting. However, Soft Gel fails to back up its attorney argument with any evidence. Moreover, Soft Gel's attorney argument is belied by the record evidence. Khan/Nazzal reported extensive testing proving why CoQ10 solubilizes in volatile essential oils. Khan/Nazzal's test results prove that a sufficient quantity of lemon oil, and thus a sufficient quantity of its main constituent, d-limonene, reduces the melting point of the CoQ10 and thereby solubilizes the liquid CoQ10 into solution with the oil.

3. Accordingly, the record evidence provides substantial evidence supporting the Board's finding that Khan/Nazzal's CoQ10-lemon oil solution contained a sufficient quantity of d-limonene suitable to solubilize the CoQ10. Further, there is substantial record evidence that Khan/Nazzal's solution does not form an emulsion unless and until it is placed in an aqueous medium, such as the gut. Therefore, the Board's finding that Khan/Nazzal anticipate claims 1-2, 6-10, 14-20 and 24 is supported by substantial evidence and should be affirmed.

Claims 1-24 would have been obvious in view of Motoyama, Soft Gel's admission regarding Motoyama, Khan, Nazzal, Steele and Davidson as evidenced by Fenaroli, Duetz, Mondello and IARC for the following reasons:

1. Motoyama taught that (i) CoQ10 is "highly soluble" in carvone; (ii) by Soft Gel's own admission, CoQ10 can be solubilized at an amount of up to 50%

by weight in carvone; (iii) carvone is a constituent of spearmint oil and peppermint oil; and (iv) CoQ10 will "readily dissolve" in spearmint oil and peppermint oil as well.

2. It would have been obvious to substitute d-limonene for the carvone, peppermint oil or spearmint oil of Motoyama, and arrive at the claimed composition, because (i) Khan/Nazzal taught that lemon oil is about equally effective as Motoyama's peppermint oil and spearmint oil in reducing the melting point of CoQ10, and thereby solubilizing the CoQ10 in the oil; (ii) Fenaroli taught that lemon oil contains 90% by weight limonene, and the form of limonene present in natural lemon oil is d-limonene; (iv) Duetz, Mondello and IARC reinforce that the limonene in lemon oil is d-limonene; and (v) Nazzal taught that chemical components of essential oils, such as limonene and carvone, can be evaluated for their potency in melting and thereby solubilizing CoQ10.

3. The skilled artisan would have been motivated to make the substitution, and would have had a reasonable expectation of success in doing so, because (i) Khan/Nazzal taught that lemon oil is about equally effective as Motoyama's spearmint oil and peppermint oil in melting and thereby solubilizing CoQ10; (ii) Soft Gel's expert admitted that it would have been "obvious to use or obvious to try lemon oil" in Motoyama's composition; (iii) Fenaroli taught that

lemon oil is 90% d-limonene; and (iii) it was known in the art that Motoyama's carvone and d-limonene are both monoterpenes.

4. Soft Gel has argued that the dependent claims are patentable over the cited references only for the same reasons raised in connection with independent claims 1 and 15. Because independent claims 1 and 15 are obvious for the reasons stated above, the dependent claims are obvious for the same reasons.

ARGUMENT

I. Soft Gel Caused the Board to Review the Unamended Claims and Therefore Cannot Seek Reversal on That Basis

Soft Gel argues that the Board's decision should be reversed because the Board failed to address the claims as amended. (Brief at 14-16.) More specifically, Soft Gel claims that "the Board completely overlooked the fact that the claims under review recite d-limonene rather than limonene." (Brief at 14.) Soft Gel is not entitled to relief because the claims that Soft Gel asked the Board to review specifically recited "limonene" and not "d-limonene." "'The impropriety of asserting a position which the [Board] adopts and then complaining about it on appeal should be obvious on its face, and litigants hardly need warning not to engage in such conduct.'" *O2 Micro Int'l, Ltd. v. Beyond Innovation Tech. Co., Ltd.*, 449 F. App'x 923, 934 (Fed. Cir. 2012) (quoting *Key Pharm. v. Hercon Labs. Corp.*, 161 F.3d 709, 715 (Fed. Cir. 1998)).

The regulations governing appeals to the Board required Soft Gel to include in its brief to the Board "[a]n appendix containing a copy of the claims to be reviewed on appeal." 37 C.F.R. § 41.67(c)(1)(viii). Soft Gel submitted its appeal brief to the Board on July 28, 2014 and included in that brief the required "Claims Appendix." (Appx1995-1997.) In its Claims Appendix, Soft Gel listed the claims as they appeared in the issued '072 patent. For example, claim 1 in Soft Gel's Claims Appendix recited "coenzyme Q-10 solubilized in ***limonene***":

> 1. A soft gelatin capsule, comprising coenzyme Q-10 solubilized in ***limonene*** to form a solution, wherein the amount of coenzyme Q-10 in said solution is about 15 percent up to about 60 percent coenzyme Q-10 by weight, with the proviso that the coenzyme Q-10 solubilized in the ***limonene*** is not in an emulsion, suspension, or elixir.

(Appx1995 (emphasis added).) The remainder of the claims set forth in Soft Gel's Claims Appendix similarly recite "limonene" rather than "d-limonene." (Appx1995-1997 (Claims 3, 6-8, 14-15, 17-18, 24).) Accordingly, the Board addressed the claims that Soft Gel asked it to review.[1]

Because Soft Gel submitted the unamended claims from the '072 patent to the Board for review, Soft Gel waived appellate review of this aspect of the Board's decision. *See O2 Micro Int'l*, 449 F. App'x at 934; *Chem. Eng'g Corp. v. Essef Indus., Inc.*, 795 F.2d 1565, 1572 (Fed. Cir. 1986) (party cannot claim error in district court's reliance on disclosures in patent when assessing infringement where that party relied on the same disclosures before the district court); *Weiner v. Rollform, Inc.*, 744 F.2d 797, 805 (Fed. Cir. 1984) (party cannot seek reversal due to testimony that was elicited by that party during cross examination).

[1]Soft Gel points to footnotes 11 and 18 in the Board's decision as illustrating "inconsistencies." (Brief at 15.) In fact, these footnotes prove that the Board reviewed the claims presented in Soft Gel's Claims Appendix. In footnote 11, the Board notes that while the "Examiner referred to d-limonene… ***the claims*** are not limited to this form, but rather recite 'limonene' which would include both the d- and l- forms." (Appx13 (emphasis added).) Similarly, in footnote 18, the Board again notes that while both the Examiner and Soft Gel refer to "d-limonene," "***the claims*** do not require d-limonene." (Appx28 (emphasis added).)

II. Soft Gel Has Not Shown That the Board's Decision Would Have Been Different if the Board Had Reviewed the Amended Claims, and Therefore Any Error Was Harmless

Soft Gel has not shown that the Board's result would be different if it had reviewed the amended claims. In order to prevail, the appellant "must not only show the existence of error, but also show that the error was in fact harmful because it affected the decision below." *In re Watts*, 354 F.3d 1362, 1369 (Fed. Cir. 2004); *see also Munoz v. State Farms, Inc.*, 69 F.3d 501, 504 (Fed. Cir. 1995) ("The correction of an error must yield a different result in order for that error to have been harmful and thus prejudice a substantial right of a party."). The harmless error rule applies to appeals from decisions rendered by the Board. *In re Watts*, 354 F.3d at 1369. All of the evidence relied upon by the Board disclosed d-limonene, either explicitly or through the disclosure of natural lemon oil which contains only d-limonene. *See infra* at 28-29. Accordingly, the evidence relied upon by the Board necessarily would have yielded the same result had the Board considered the amended claims reciting "d-limonene" instead of "limonene."

There are two enantiomers of limonene, d-limonene and l-limonene. The evidence in the record established that lemons produce only one enantiomer, d-limonene. (Appx2081-2082.) Soft Gel argued in support of patentability of the claims of the related '583 patent that "lemon oil contains d-limonene" and distinguished this from l-limonene which "is not used as a solvent but rather is

used as a botanical insecticide." (Appx2073.) Jarrow also submitted substantial evidence that lemon oil contains a high percentage of d-limonene. *See* Duetz ("d-limonene is the main constituent of orange and lemon peel oil (92 to 96%)," (Appx1987); Mondello (d-limonene (i.e., R(+) limonene) comprises 98.1% of lemon oil, (Appx1983 at Table 6); and IARC (d-limonene comprises 98-100% of the limonene in the *Rustaceae* citrus oil family, which includes lemons. (Appx1106.)

Soft Gel concedes that the Board repeatedly refers to "d-limonene" throughout its analysis of the claims. (Brief at 14-15.) Moreover, the Board's analysis did not hinge on any difference between "limonene" and "d-limonene." Soft Gel does not explain how the Board's analysis would differ, or why the Board would arrive at a different result, if the Board had analyzed the amended claims. Accordingly, any error was harmless and the Board's decision should be affirmed. *In re Watts*, 354 F.3d at 1369 (finding error harmless where appellant had not identified any argument or evidence that would yield a different result on remand).

III. The Examiner's Rejections of the Claims Based Upon Khan '786 in Grounds 1-3 of the RAN Should Be Affirmed for the Same Reasons That the Rejections Based Upon Nazzal in Grounds 4-6 Should Be Affirmed

In its decision, the Board did not address the rejections in Grounds 1-3 of the RAN.[2] When the Board does not specifically address a ground of rejection in its decision, the examiner's rejection is deemed to be affirmed by the Board for the reasons stated by the examiner. *In re Rijckaert*, 9 F.3d 1531, 1534 n.4 (Fed. Cir. 1993) ("The Board did not specifically address the rejection of claim 6; therefore, claim 6 was considered to be affirmed for the reasons stated by the examiner."). Accordingly, the rejections in Grounds 1-3 of the RAN are deemed affirmed by the Board, and it is appropriate for this Court to review the examiner's rejections in this appeal. *In re Nielsen*, 816 F.2d 1567, 1571 (Fed. Cir. 1987)("[U]nless an examiner's rejection was expressly reversed by the Board, it was appropriate for the court to consider that rejection."); 37 C.F.R.§ 41.77(a) ("The affirmance of the rejection of a claim on any of the grounds specified constitutes a general affirmance of the decision of the examiner on that claim, except as to any ground specifically reversed.").

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[2]In Ground 1, the Examiner rejected claims 1-3, 6-10, 14-20 and 24 as anticipated by Khan '786 as evidenced by Fenaroli, Duetz, Mondello and IARC. (Appx1401-1404.) In Ground 2, the Examiner rejected claims 4, 11, and 21 as obvious in view of Khan '786 and Steele as evidenced by Fenaroli, Duetz, Mondello and IARC. (Appx1404-1405.) In Ground 3, the Examiner rejected claims 12 and 22 as obvious in view of Khan '786, Motoyama, and Patent Owner's admission on Motoyama as evidenced by Fenaroli, Duetz, Mondello and IARC. (Appx1405.)

The rejections in Grounds 1-3 are identical to the rejections in Grounds 4-6 except that Khan is cited in Grounds 1-3 while Nazzal is cited in Grounds 4-6.[3] (Appx4-5.) Soft Gel concedes that the "relevant disclosures of Nazzal and Khan are nearly identical" (Brief at 5), and Soft Gel has not identified any differences in the references that would warrant treating Grounds 1-3 differently from Grounds 4-6. Accordingly, the Examiner's rejections in Grounds 1-3 should be affirmed for the same reasons that the rejections in Grounds 4-6 should be affirmed.

IV. There is Substantial Evidence Supporting the Finding that Khan/Nazzal Anticipate Claims 1-2, 6-10, 14-20 and 24 Requiring Affirmance of the Anticipation Rejections

A. Standard of Review on Anticipation

Anticipation is a question of fact reviewed for substantial evidence. *In re Mousa*, 479 F. App'x 348, 352 (Fed. Cir. 2012) (citing *In re Aoyama*, 656 F.3d 1293, 1296 (Fed. Cir. 2011). Substantial evidence is "relevant evidence" that "a reasonable mind might accept as adequate to support a conclusion.'" *In re Gartside*, 203 F.3d 1305, 1312 (Fed. Cir. 2000). "Substantial evidence is

[3]In Ground 4, the Examiner rejected claims 1-3, 6-10, 14-20 and 24 as anticipated by Nazzal as evidenced by Fenaroli, Duetz, Mondello and IARC. (Appx1406-1408.) In Ground 5, the Examiner rejected claims 4, 11, and 21 as obvious in view of Nazzal and Steele as evidenced by Fenaroli, Duetz, Mondello and IARC. (Appx1409.) In Ground 6, the Examiner rejected claims 12 and 22 as obvious in view of Nazzal, Motoyama, and Patent Owner's admission on Motoyama as evidenced by Fenaroli, Duetz, Mondello and IARC. (Appx1409-1410.)

something less than the weight of the evidence but more than a mere scintilla of evidence." *Id.*

"The correct standard is not what the court would decide in a *de novo* appraisal, but whether the administrative determination is supported by substantial evidence on the record as a whole." *McMillan v. Dep't of Justice*, 812 F.3d 1364, 1371 (Fed. Cir. 2016). *See also In re NTP, Inc.*, 654 F.3d 1279, 1292 (Fed. Cir. 2011) ("This court does not reweigh evidence on appeal, but rather determines whether substantial evidence supports the Board's fact findings."). "[T]he possibility of drawing two inconsistent conclusions from the evidence does not prevent an administrative agency's finding from being supported by substantial evidence." *Crash Dummy Movie, LLC v. Mattel, Inc.*, 601 F.3d 1387, 1390 (Fed. Cir. 2010) (quoting *Consolo v. Fed. Maritime Comm'n*, 383 U.S. 607, 620 (1966)).

B. Legal Standard for Anticipation and Burden Shifting

"Anticipation of a claim under 35 U.S.C. § 102 occurs when each claimed element and the claimed arrangement or combination of those elements is disclosed, inherently or expressly, by a single prior art reference." *In re Mousa*, 479 F. App'x at 352 (citing *Therasense, Inc. v. Becton, Dickinson & Co.*, 593 F.3d 1325, 1332 (Fed. Cir. 2010)). "A reference inherently discloses an element of a claim 'if that missing characteristic is *necessarily* present, or inherent, in the single anticipating reference.'" *Id*. (quoting *Schering Corp. v. Geneva Pharms.*, 339 F.3d

1373, 1377 (Fed. Cir. 2003)) (emphasis original). "'Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" *Id*. (quoting *Therasense*, 593 F.3d at 1332).

"The Examiner has the burden of providing reasonable proof that a claim limitation is an inherent characteristic of the prior art." *In re Mousa*, 479 F. App'x at 352 (citing *In re Best*, 562 F.2d 1252, 1254-55 (C.C.P.A. 1977) and *Crown Operations Int'l, LTD v. Solutia Inc.*, 289 F.3d 1367, 1377 (Fed. Cir. 2002)). "The Examiner meets this burden of production by adequately explaining the shortcomings it perceives so that the applicant is properly notified and able to respond." *Id*. (quoting *In re Jung*, 637 F.3d 1356, 1362 (Fed. Cir. 2011) (internal quotations omitted). "The burden of proof then shifts to the applicant 'to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on.'" *Id*. (quoting *Best*, 562 F.2d at 1254-55); *see also In re Schreiber*, 128 F.3d 1473, 1478 (Fed. Cir. 1997) (holding that once the Examiner established a *prima facie* case of anticipation, the burden of proof was properly shifted to the inventor to rebut the finding of inherency).

C. Substantial Evidence Supports the Finding That Khan/Nazzal Solubilize CoQ10 to Form a Solution[4]

1. Khan/Nazzal Disclose That Volatile Essential Oils Reduce the Melting Point of CoQ10, and That the Liquefied CoQ10 Is Solubilized in the Volatile Essential Oils to Form a Solution

CoQ10 consists of solid crystals at or below body temperature (about 37°C). (Appx1151-1152 at ¶3).) Prior to the invention of Khan/Nazzal, fixed oils were utilized to solubilize CoQ10, but they were not able to solubilize the CoQ10 at amounts above about 5-10%. (*Id*.) Because of CoQ10's poor solubility in fixed oils, it tended to recrystallize, particularly at higher concentrations, which reduced its bioavailability. (*Id*.)

Khan/Nazzal discovered that a sufficient amount of volatile essential oil, such as lemon oil, reduces the melting point of CoQ10 to 37°C or below, to thereby liquefy the CoQ10 and solubilize it in the volatile essential oil at or below body temperature. (Appx1152 at ¶4.) Khan/Nazzal's discovery of the depression of CoQ10's melting temperature in the presence of volatile essential oils was significant in terms of administration because human body temperature is typically about 37°C. (Appx1152-1153 at ¶6.) The depression in the melting temperature

[4]During prosecution of the reexamination, Soft Gel did not distinguish between the disclosures of Khan and Nazzal, but rather argued that their disclosures are the same and made the same arguments for both publications. (Appx980.) In light of this, the Examiner affirmed the anticipation rejection over Khan for the same reasons as those set forth for Nazzal. (Appx1401-1410.)

of CoQ10 meant that higher amounts of molten CoQ10 could be solubilized and remain solubilized at physiologically relevant temperatures. (*Id*.) The increased solubility of CoQ10 could improve its overall bioavailability, and meant that less CoQ10 had to be administered in order to achieve a systemic concentration that provides therapeutic benefits. (*Id*.)

2. Khan/Nazzal Proved Through Extensive Testing That the CoQ10 Is Melted and Thereby Solubilized to Form a Solution

Khan/Nazzal conducted extensive Differential Scanning Colorimetry ("DSC") tests demonstrating that when CoQ10 is mixed with a sufficient amount of volatile essential oil, the CoQ10 melts, i.e., it undergoes a phase change from solid (crystals) to liquid, and the liquid CoQ10 is thereby solubilized in the essential oil to form a solution. (Appx1153-1157 at ¶¶9-15, Appx481-483 at FIGS. 1-4, Appx494 at 3:29-37 and FIGS. 1-4, Appx322-330.) DSC was a well-known technique for measuring the melting temperature of ingredients in mixtures. (Appx1153-1154 at ¶9).) FIG. 3 of Khan (below) shows the thermograms for samples of CoQ10 in peppermint oil, and Figure 4.11 of Nazzal (below) shows the thermograms for samples of CoQ10 in lemon oil. (Appx328, Appx482.) Each curved line is the thermogram of a sample binary mixture containing a respective ratio of CoQ10 to essential oil. (*Id*.) The upward peak in each thermogram indicates the temperature at which the CoQ10 melts, i.e., the temperature at which

it undergoes a transition from solid (crystals) to liquid at the respective amount of essential oil. (Appx1154 at ¶10.) The line to the right of the peak in each thermogram indicates that the CoQ10 is liquid at the temperatures over which the line extends. *Id*. As can be seen, progressively increasing the amount of essential oil as compared to CoQ10 in the samples tested progressively decreased the melting temperature of the CoQ10. (Appx1156-1157 at ¶14, *see also* Appx483 at FIG. 4, Appx495 at 6:36-40 ("An increase in percent essential oil causes a gradual decrease in the melting temperature of CoQ10. At sufficient concentration of the volatile oil it becomes feasible to convert CoQ10 to an **oily phase** at or below body temperature." (emphasis added), Appx13 at FF1-FF4.)

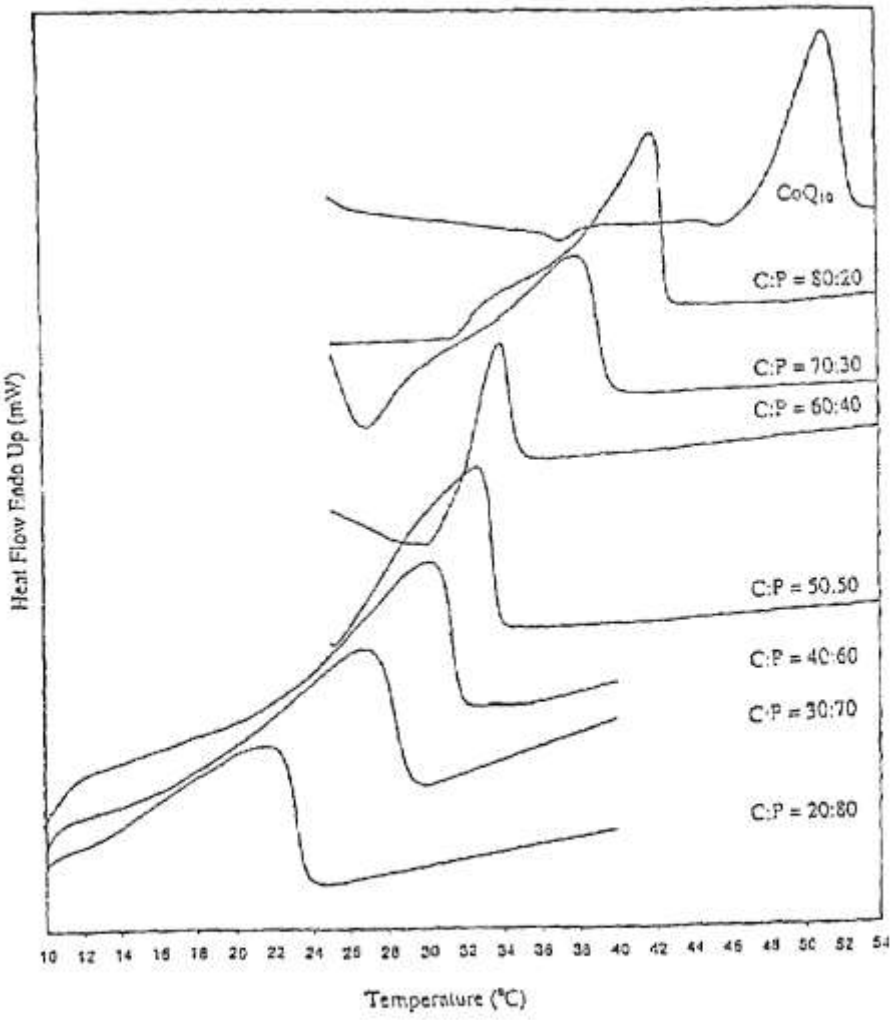

FIG. 3

FIG. 3 of Khan above shows the DSC thermograms for binary combinations of CoQ10 and peppermint oil at ratios of "C:P" (i.e., CoQ10:peppermint oil) from 80:20 to 20:80. (Appx1155 at ¶12.) The thermograms of FIG. 3 demonstrate that increasing the amount of peppermint oil as compared to CoQ10 decreases the melting point of the CoQ10 as follows:

Ratio of CoQ10 to Peppermint Oil (C:P; w/w %)	**Melting Point of CoQ10 (°C)**
80:20	42°C
70:30	38°C
60:40	34°C
50:50	32°C
40:60	30°C
30:70	26°C
20:80	22°C

Figure 4.11 of Nazzal below shows the DSC thermograms for binary mixtures of CoQ10 and lemon oil at ratios of "C:L" (i.e., CoQ10:lemon oil) from 80:20 to 40:60. (Appx328.)

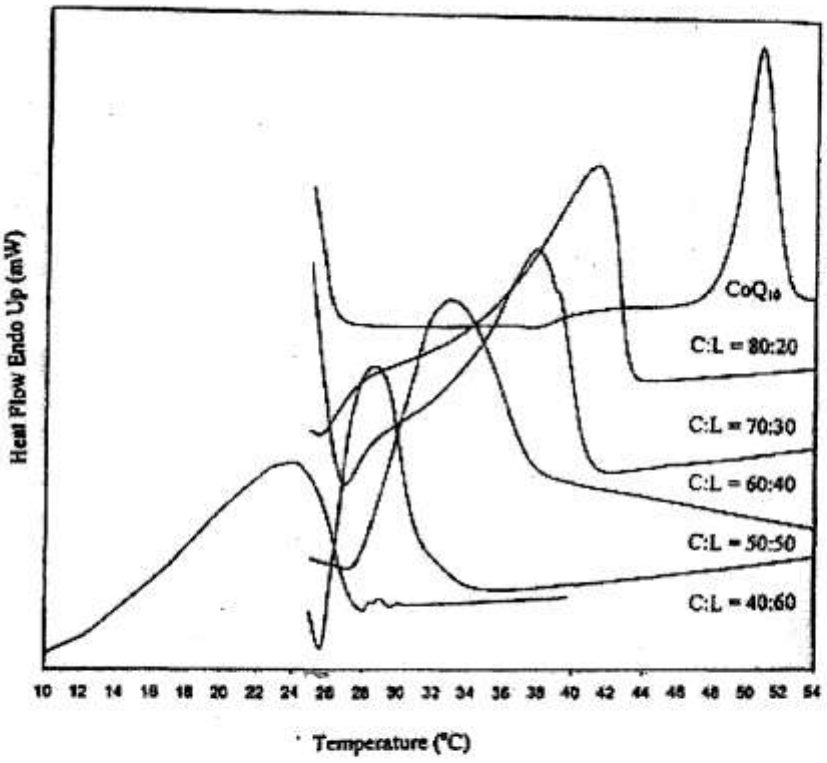

Figure 4.11. DSC thermograms of Coenzyme Q_{10}, lemon oil, and their binary mixtures. Ratios by weight

The thermograms of Figure 4.11 demonstrate that increasing the amount of lemon oil as compared to CoQ10 decreases the melting point of the CoQ10 as set forth in the table below. (Appx328, Appx1156-1157 at ¶14.) The last three binary mixtures include CoQ10 in an amount of 60%, 50% and 40% by weight, respectively, and therefore each falls within the range of "about 15 percent up to about 60 percent … by weight," as recited in the '072 claims.

Ratio of CoQ10 to Lemon Oil (C:P; W/W %)	**Melting Point of CoQ10 (°C)**
80:20	42°C
70:30	37°C
60:40	33°C
50:50	27°C
40:60	25°C

3. Khan/Nazzal Explicitly State That the CoQ10 is Melted and Thereby Solubilized

Khan/Nazzal explicitly state that the melted CoQ10 is "solubilized" in the volatile essential oil. Khan states, in pertinent part, that the orally administered dietary supplement comprises "a sufficient amount of volatile essential oil **to solubilize the ubiquinone**, and **wherein said volatile essential oil is present in a sufficient amount to reduce the melting point of ubiquinone to** 37° C or below, and **thereby solubilize the ubiquinone** comprised in in the orally administered dietary supplement at or below body temperature." (Appx502 at 20:26-31 (emphasis added).) Dr. Nazzal explains in his Declaration that when the CoQ10 is melted to a liquid, it is solubilized in the essential oil. (Appx18, Appx1152 at ¶¶4,5, *see also* Appx1152-53 at ¶6 ("higher amounts of molten CoQ10 can be dissolved or solubilized in additional excipients, and remain solubilized at physiologically relevant temperatures").) *See Kennametal, Inc. v. Ingersoll Cutting Tool Co.*, 780 F.3d 1376, 1382 (Fed. Cir. 2015) (upholding board's

anticipation determination where prior art "expressly recites" claim limitations); *Krippelz v. Ford Motor Co.*, 667 F.3d 1261, 1267-68 (Fed. Cir. 2012) (reversing denial of JMOL on anticipation where prior art reference had "language [that] expressly satisfies the requirement" of the claim limitation).

4. Khan/Nazzal Teach That the SNEDDS "Improves the Dissolution … of CoQ10"

Khan/Nazzal describe one embodiment of the invention as a "self-nanoemulsified drug delivery system (SNEDDS)" containing the following four ingredients: "[i] polyoxyl 35 castor oil (herein referred to as 'Cremophor') as a surfactant, [ii] a medium chain mono- and diglyceride (herein referred to as 'Capmul') as a co-surfactant, [iii] essential oils, and [iv] a pharmacologically effective drug." (Appx493 at 2:32-39.) Khan discloses that the volatile essential oil is preferably selected from a group including lemon oil, and the preferred pharmacologically effective drug is CoQ10. (Appx493 at 2:43-51.) Khan does not teach the melting point depression method as an alternative to dissolving CoQ10, as argued by Soft Gel. (Brief at 31-38.) To the contrary, Khan teaches that the melting point depression method improves the dissolution of CoQ10: "In a eutectic-based SNEDDS, **the melting point depression method** allows the oil phase containing the drug itself to melt at body temperature from its semisolid consistency…. The SNEDDS **improves the dissolution of** poorly soluble

compounds, such as the preferred **CoQ10**." (Appx493 at 2:55-61 (emphasis added), *see also* Appx322.)

In sum, there is more than sufficient "'relevant evidence' that 'a reasonable mind might accept as adequate to support a conclusion" that Khan/Nazzal solubilize the CoQ10 to form a solution. *Gartside*, 203 F.3d at 1312.

D. Substantial Evidence Supports the Finding That the Lemon Oil of Khan/Nazzal Contained a Sufficient Quantity of d-Limonene Suitable to Solubilize the CoQ10

1. Substantial Evidence Supports the Board's Finding That d-Limonene Is the Main Constituent of Lemon Oil[5]

Fenaroli teaches that lemon oil comprises approximately 90% limonene. (Appx1624 ("more than 40 constituents have been identified in the [lemon] oil, which contains approximately 90% limonene (by weight)"), *see also* Appx21 at FF10.) Soft Gel submitted Fenaroli to the PTO, and argued Fenaroli's teachings with respect to d-limonene in order to obtain allowance of the claims in the related '583 patent. (Appx2071, Appx2088.) Soft Gel is therefore bound by Fenaroli's teachings with respect to d-limonene. *In re Applied Materials, Inc.*, 692 F.3d 1289, 1297 (Fed. Cir. 2012) (upholding Board's reliance on patentee's admissions regarding teachings of prior art, and concluding that these teachings required invalidating the patent); *see also Ex Parte Kraft*, No. 2009-014339, 2012 WL 1071565 at *1 (B.P.A.I. March 26, 2012) (rejecting applicant's proposed claim

[5](Appx21-23.)

construction because "the Examiner correctly points out that [applicant's] own Wikipedia exhibit supports a broader construction").

The other references of record establish that: (i) "d-limonene is the main constituent of orange and lemon peel oil (92 to 96%)" (Appx1987), (ii) d-limonene comprises 98.1% of lemon oil (Appx1983 at Table 6), (iii) d-limonene comprises 98-100% of the limonene in the *Rustaceae* citrus oil family, which includes lemon (Appx1106, *see also* Appx22 at FF11), and (iv) citrus fruits, such as lemons, only produce d-limonene, not l-limonene (Appx1987, Appx2081). Further, during prosecution of the related '583 patent, Soft Gel argued to the PTO that the limonene in lemon oil contains only d-limonene, and that l-limonene "is used as a botanical insecticide." (Appx2073.)

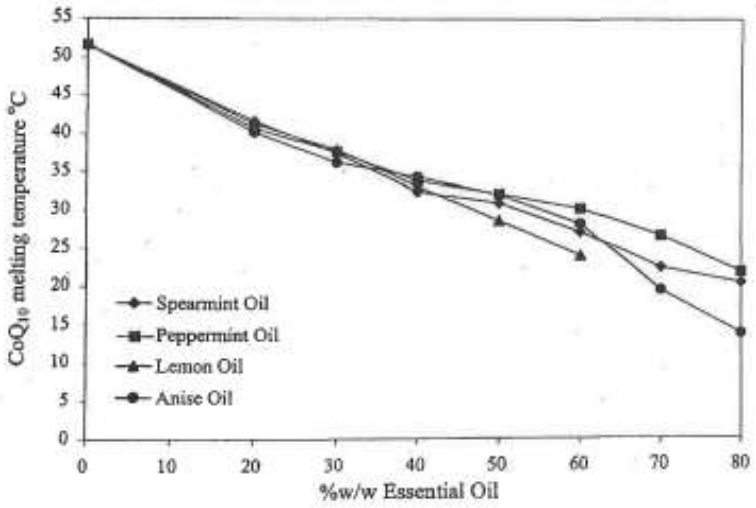

Figure 4.13. The temperature/composition phase diagram of Coenzyme Q_{10}-essential oil binary systems determined by DSC

Khan/Nazzal's DSC testing is summarized at Figure 4.13 of Nazzal above (which is FIG. 4 of Khan). (Appx330.) The temperature at which an endothermic peak (i.e., melting point) was observed for CoQ10 crystals for each respective volatile essential oil is plotted as a function of the relative ratio of CoQ10:Essential Oil. Dr. Nazzal explained that "lemon oil, which is reported to be 90% d-limonene, reduces the melting temperature of CoQ10 to below about 37ºC at a 'C:L' ratio (i.e., CoQ10:Lemon oil) of 60:40. Because lemon oil is 90% d-limonene, the observed depression in CoQ10's melting temperature can be attributed to d-limonene." (Appx1156-1157 at ¶14.)

The Board adopted the Examiner's findings that (i) lemon oil contains 90% or more limonene; (ii) d-limonene constitutes 92-96% of lemon peel oil; and (iii) d-limonene amounts to 98-100% of the limonene in lemon oil. (Appx22 at FF11.) Based on these findings, the Examiner found that (i) the binary composition of CoQ10 and lemon oil as shown in Nazzal Figure 4.13/Khan FIG. 4 (above), contains "about 36%, 45% and 54% by weight d-limonene (in 40%, 50% and 60% by weight lemon oil) in a mixture with 60%, 50% and 40% by weight of coenzyme Q10 respectively;" and (ii) in the binary composition "coenzyme Q10 melts and solubilizes at about 33°C, 26°C and 24°C respectively (Fig. 4), indicating that d-limonene (lemon oil) is suitable for dissolving coenzyme Q10 at ambient temperature or below." (Appx22, Appx1156-1157 at ¶14.) For the reasons summarized above, these findings are supported by substantial evidence.

2. Soft Gel's Argument That d-Limonene is Not the Main Constituent of Lemon Oil is Without Evidentiary Support

Soft Gel's argument falls flat because all of the evidence of record – including the evidence submitted by Soft Gel – supports the Board's finding that d-limonene is the main constituent of lemon oil.

Soft Gel selectively quotes the Board in arguing that it "acknowledged that 'Nazzal does not expressly teach that the Q10 dissolves in limonene.'" (Brief at 16.) Significantly, Soft Gel crops from its quotation the remainder of the Board's sentence, which reads, in pertinent part, as follows: "while Nazzal does not

describe its composition with the same terms recited in the claim, the claimed composition would be a necessary result of making the composition described in Nazzal." (Appx15.)

Soft Gel goes on to argue that the Board's factual finding should be reversed because of the nineteen tests conducted by Lota on various species and cultivars of lemon oil, one revealed 38.1% d-limonene. (Brief at 20.) Even in that sample, however, d-limonene was the largest constituent, which caused Lota to state that "[l]imonene was **always the main constituent** (38.1-95.8%) of all oils." (Appx1262 (emphasis added).) Soft Gel fails to cite any evidence showing that d-limonene is not the main constituent of lemon oil.[6]

The fact that the Board stated in connection with a different patent that d-limonene "is one of the main constituents of lemon oil" does not change the outcome in this case. (Brief at 20-21.) First, the Board did not cite any evidence in the other case in which d-limonene was not the largest or main constituent of lemon oil. The only reference cited by Soft Gel to support its argument is Lota, but Lota states no such thing. Rather, Lota states that limonene is "always the main constituent." (Appx1262.) Second, all of the evidence of record establishes that d-limonene is the main constituent of lemon oil. *See supra* at 28-31.

[6]Curiously, Soft Gel points out that IARC discloses that limonene is a minor component of citrus peel oil from bergamot. (Brief at 20.) A bergamot is a type of orange and has no relevance to the issues in this proceeding.

Accordingly, the Board's finding that d-limonene is the main constituent of lemon oil is supported by substantial evidence and must be affirmed.

Moreover, the Board found that, even if the lemon oil used in Khan/Nazzal was not 90% d-limonene, it did not undermine the Examiner's anticipation rejection. (Appx23-24.) The Board found "the evidence is that 1) lemon oil solubilizes and dissolves Q10, and 2) limonene is [the] principal component of it, giving the Examiner reasonable factual basis to conclude that even lemon oils with less than 90% limonene would have sufficient d-limonene present to dissolve Q10." (Appx24.) Whether phrased as "the main constituent" or "the principal component," d-limonene is the largest constituent in every lemon oil described in the references of record. Accordingly, the Board's findings are supported by substantial evidence, and the rejection of the claims as anticipated by Khan/Nazzal must be affirmed.

3. The CoQ10 is Necessarily Solubilized in the d-Limonene of the Lemon Oil, as Claimed

Claims 1 and 15 simply require, in pertinent part, that the composition comprise "a sufficient quantity of d-limonene suitable to solubilize said coenzyme Q-10…." As indicated above, d-limonene is the main constituent of lemon oil, Khan/Nazzal's CoQ10 is solubilized in the lemon oil, and therefore the CoQ10 necessarily is solubilized in the d-limonene of the lemon oil. Since the CoQ10 is

solubilized in the d-limonene of the lemon oil, it necessarily follows that a sufficient quantity of d-limonene is present in the lemon oil to solubilize it.

Soft Gel argues that something other than the d-limonene is responsible for solubilizing the CoQ10, but fails to identify what that is. (Brief at 39-41.) However, even if Khan/Nazzal's composition included a component in addition to d-limonene responsible for solubilizing the CoQ10 (which Soft Gel has not identified), the claim does not preclude any such additional component. Claim 1 includes the transitional phrase "comprising," and therefore the composition can include ingredients in addition to those recited in the body of the claim. *Vivid Tech. Inc. v. Am. Sci. & Eng'g Inc.*, 200 F.3d 795, 811-812 (Fed. Cir. 1999) ("the signal 'comprising' is generally understood to signify that the claims do not exclude the presence in the accused apparatus or method of factors in addition to those explicitly recited"). Thus, if the compositions of Khan/Nazzal did include additional components that contributed to solubilizing the CoQ10 (which Soft Gel has not identified), the compositions nevertheless had a sufficient quantity of d-limonene suitable to solubilize the CoQ10 in those compositions.

In sum, there is more than sufficient "'relevant evidence' that 'a reasonable mind might accept as adequate to support a conclusion" that the lemon oil of Khan/Nazzal contained a sufficient quantity of d-limonene suitable to solubilize the CoQ10. *Gartside*, 203 F.3d at 1312.

E. Substantial Evidence Supports the Finding that Khan/Nazzal's Solution is Not Part of An Emulsion, Suspension or Elixir

Khan and Nazzal teach a combination of a surfactant, co-surfactant, essential oil and CoQ10, referred to as "SNEDDS", that is "introduced into soft or hard gel capsules." (Appx493 at 2:33-51, Appx281-282.) Substantial evidence supports the finding that the SNEDDS does not form an emulsion until it is introduced into an aqueous environment, such as the gut. Khan describes two different examples of SNEDDS in different dosage forms, referred to as "Example I" and "Example II." (Appx495-502.) Example I teaches that CoQ10 may be melted and thereby solubilized in lemon oil to form an "oily melt." (Appx495 at 6:20-21.) Khan further describes a surfactant and co-surfactant that are added to the oily melt as "emulsifiers." (Appx495-496 at 6:65-7:3.) As defined by the Examiner, and not disputed by Soft Gel, emulsifiers are compounds that stabilize emulsions. (Appx1398.) The emulsifiers do not create an emulsion themselves; rather, they require the presence of another liquid, such as water, to create an emulsion. (Appx493 at 2:52-55.)

Nazzal similarly describes preparation of the SNEDDS of Example I as follows: "A series of self-emulsifying systems were prepared with varying concentrations of the oily mix (37.5-60%), Cremophor EL (0-62.5%), and Capmul MCM-C8 (0-62.5%). The oily mix consisted of CoQ10 and lemon oil at a ratio of 50:50. * * * Cremophor EL and Capmul MCM-C8 were added to the oily mix….

While molten, formulations with different concentrations of surfactant, co-surfactant, and the oil mix, each containing CoQ10 at a final loading of 30 mg, were filled into size 4 HPMC capsules." (Appx281.) "The extra time provided by HPMC capsules allows the formula to completely melt at body temperature before it is exposed to body fluids." (Appx342.)

The Examiner and the Board relied on Khan/Nazzal's teaching of Example I to reject the claims as anticipated. (Appx10-13, Appx1402-1403.) In connection with Example I, Khan only describes emulsification of the SNEDDS when it is put into an aqueous environment, such as in the gut. (Appx493 at 2:52-61, Appx496 at 7:62-67.) Specifically, Khan states that the SNEDDS – the mixture of oil, surfactant, co-surfactant and CoQ10 – "forms a fine oil-in-water emulsion when introduced into an aqueous medium under gentle agitation." (*Id.*) Nazzal similarly states in connection with Example I: "To assess the self-emulsification properties, formulation (50 mg) pre-melted at 37°C was introduced into 100 ml of water…. The tendency to spontaneously form a transparent emulsion was judged…." (Appx282, *see also id.* ("Each formulation … was diluted with water…. The resultant emulsions was [sic] evaluated….").) Accordingly, Khan/Nazzal teach that the SNEDDS does not form an emulsion until it is introduced into an aqueous medium. (Appx9-13.)

Soft Gel ignores Khan/Nazzal's teaching of Example I and argues, based on a passage in connection with Example II, that the SNEDDS is an "emulsion" before it is introduced into the gut. (Brief at 7-8.) Significantly, Example II was not used by the Examiner or the Board to reject the claims, and should not be used by this Court either. The passage cited by Soft Gel in connection with Example II is internally inconsistent and ambiguous, and Soft Gel's argument in connection with that passage should be rejected. Further, Example II should not be conflated with the clear teaching in connection with Example I where the SNEDDS does not form an emulsion until it is introduced into an aqueous environment.

Khan describes Example II as a powdered solid dosage form. (Appx498 at 11:52-57.) In describing preparation of the solid dosage form, Example II refers to the combination of surfactants, essential oil, and CoQ10 as both an "emulsion" and a "transparent solution." (Appx498 at 11:61-12:1.) Soft Gel, of course, latches on to the word "emulsion" to argue that Khan teaches an emulsion when the oily melt is mixed with the surfactants, and ignores the fact that Khan describes the same mixture in the same passage as a "transparent solution." Khan explicitly states that the purported "emulsion" formed a "transparent solution." (*Id.*) The terms "emulsion" and "solution" were defined in this proceeding, the definitions are not disputed, and the terms are mutually exclusive. Specifically, a "solution" is "a homogeneous mixture of two or more substances." (Appx1398.) An "emulsion,"

on the other hand, is "a substantially permanent mixture of two or more liquids which do not normally dissolve in each other but which are held in suspension, one in the other. The suspension is usually stabilized by small amounts of additional substances known as emulsifiers." (*Id*.) Thus, a "transparent solution" cannot be an "emulsion," and vice versa. Accordingly, the passage relied on by Soft Gel in connection with Example II is internally inconsistent and ambiguous, and Soft Gel's argument based on that passage must be rejected. Example II is separate and distinct from Example I, does not impact the teaching of Example I, and should not be conflated with that teaching. *See Krippelz*, 667 F.3d at 1267-69 (district court should have granted JMOL of anticipation based on express teaching of claim limitation in prior art, because expert testimony that claim was not anticipated was limited to "just one embodiment").

Soft Gel's reliance on the Board's rejection in the related '826 patent is misplaced. (Brief at 28.) That decision was issued prior to the oral argument before the Board in this proceeding. Significantly, during oral argument in this proceeding, Soft Gel's argument in connection with Example II was squarely addressed, the above arguments were presented to the Board, and the Board affirmed the rejection based on Khan/Nazzal's above-described teachings of Example I. (Appx3460-3477.) Clearly, the Board recognized that its reliance on the passage in Example II in connection with the '826 patent was in error for the

reasons set forth in its subsequent decision in this proceeding (Appx9-13), and the Board elected not to make the same error in this proceeding.[7]

F. The Board Did Not Improperly Shift the Burden of Proof, but Rather Properly Shifted the Burden of Production

"[W]hen the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990). "Such a burden-shifting framework is fair because of 'the PTO's inability to manufacture products or to obtain and compare prior art products.'" *Howmedica Osteonics Corp. v. Zimmer, Inc.*, 640 Fed. Appx. 951, 957 (Fed. Cir. 2016) (quoting *In re Best*, 562 F.2d 1252, 1255 (C.C.P.A. 1977)). "A sound basis for believing in identity does not turn on absolute certainty; rather, a sound basis for finding identity requires the Board to make sufficient factual findings, such that it can reasonably infer that the prior art product and that of the patent at issue are the same." *Howmedica*, 640 F. App'x at 958 (citing *In re Spada*, 911 F.2d at 708).

The evidence before the Board established that (i) Khan/Nazzal's lemon oil reduced the melting point of the CoQ10; (ii) the CoQ10 transitioned from a liquid to a solid at or below body temperature; (iii) the liquefied CoQ10 was thereby

[7]An appeal of the Board's rejection of all claims of the '826 patent is pending before this court in Case 17-1051. Reversal of the Board's error in that case regarding Example II of Khan may provide an alternate grounds to affirm the rejection of the '826 patent.

solubilized in the lemon oil; (iv) d-limonene is the main constituent of lemon oil; and (v) the CoQ10 is necessarily solubilized in the d-limonene of the lemon oil. *Supra* at 20-31. The Board clearly made sufficient factual findings to reasonably infer that Khan/Nazzal's solution of CoQ10 and d-limonene was the same as the claimed solution, and therefore the burden properly shifted to Soft Gel to show that they are not. *See Howmedica*, 640 Fed. Appx. at 958 (upholding Board's shifting of burden of production onto applicant, because the Board need only put forth "sufficient factual findings, such that it can reasonably infer" they are the same); *In re Mousa*, 479 F. App'x at 352 (upholding Board's shifting of burden of production onto patentee, because Board's factual findings were sufficient to provide a "sound basis" for anticipation rejection).

Soft Gel argues that the PTO improperly shifted the burden of proof when it found that it had "not demonstrated 'any difference between the prior art binary mixtures of coenzyme Q10 and lemon oil (d-limonene) and the claimed composition comprising coenzyme Q10 and d-limonene.'" (Appx12.) However, the Examiner found that Khan/Nazzal disclose the same solution of CoQ10 and d-limonene) as recited in the claims. (Appx1416.) The Examiner therefore properly required Soft Gel to produce some evidence to support its argument that the claimed and prior art solutions are not the same. Soft Gel failed to produce a shred of evidence to back up its claim. Rather, Soft Gel asserted – based only on

attorney argument – that the "mechanism" of its claimed composition is different, and that the CoQ10 in the claimed composition is purportedly solubilized without melting. Further, Soft Gel's attorney argument is belied by the evidence of record. Khan/Nazzal engaged in extensive DSC testing to prove why CoQ10 solubilizes in volatile essential oils. *Supra* at 21-26. Khan/Nazzal's test results prove that a sufficient amount of lemon oil, and thus a sufficient amount of its main constituent, d-limonene, reduces the melting point of the CoQ10 to thereby solubilize the melted CoQ10 in the oil. *Supra* at 26-34.

Soft Gel's argument that "the mechanism by which one gets to a liquid solution is an important limitation … that cannot be ignored," misses the mark. (Brief at 38.) First, for the reasons summarized above, there is no evidence of a different "mechanism." Second, where the product described in the prior art is the same as the claimed product, as is the case here, the process (or "mechanism") by which the product is made is not a patentable distinction. *See Medicines Co. v. Hospira, Inc.*, 827 F.3d 1363, 1374 (Fed. Cir. 2016) ("For validity purposes, the 'invention' in a product-by-process claim is the product."); *In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985) ("If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process."). The Board properly

found that even if the "mechanisms" were different (of which there is no proof), "it is the result which is claimed." (Appx21.)

Soft Gel argues that the Board improperly shifted the burden of proof because it stated that Soft Gel (i) "fails to provide evidence that… the amounts of d-limonene would have been insufficient to dissolve the Q10" (Appx24); and (ii) "has not provided adequate evidence that subsequent work by Khan's group using d-limonene rather than lemon oil reasonably means that Khan did not believe the lemon oil in Nazzal was not predominantly d-limonene." (Appx26.)

First, the Board properly placed the burden of production on Soft Gel and requested that Soft Gel back up its attorney argument with factual support. Mere attorney argument is not sufficient. *elcommerce.com v. SAP AG*, 745 F.3d 490, 506 (Fed. Cir. 2014) ("Attorney argument is not evidence."). Unable to identify any evidence to support its arguments, Soft Gel engages in rank speculation about Khan's possible motivation in conducting the tests described in Khan 2004. (Brief at 21-23.) This too is mere attorney argument, unsupported by any evidence.

G. The Board Properly Took Judicial Notice of a Standard Text

The Board took judicial notice of the definition of "dissolve" in a standard chemistry text to provide further support for the Examiner's finding "that melting is 'closely related' to dissolving because both involve energy changes," and that both melting and dissolving result in solubilization of CoQ10. (Appx17-18.)

Soft Gel argues that the anticipation rejection should be reversed because it did not have an opportunity to address this textbook definition of "dissolve." (Brief at 25 n.4.) However, in affirming the Examiner's rejection, the Board was entitled to take judicial notice of such a fact from a standard text to "fill in the gaps" which might exist in the evidentiary showing made by the Examiner to support the rejection. *See In re Boon*, 439 F.2d 724, 727-28 (C.C.P.A. 1971) (affirming Board's judicial notice of dictionary definition to provide additional support for Examiner's rejection).

In addition, the fact that the Board took judicial notice of the textbook definition of "dissolve" did not change the thrust of the rejection, and Soft Gel had ample opportunity to respond to that rejection. Where a patent owner has previously had a fair opportunity to respond to the "thrust of the rejection," the Board's supplementation of the Examiner's decision through judicial notice does not require that the patent owner be provided another opportunity to respond. *Belden Inc. v. Berk-Tek LLC,* 805 F.3d 1064, 1080 (Fed. Cir. 2015); *In re Kronig & Scharfe*, 539 F.2d 1300, 1303 (C.C.P.A. 1976) (rejection is not "new" where appellant had fair opportunity to address the rejection with the Examiner and the Board).

First, the thrust of the ground for rejection always has remained the same – melting and dissolving are closely related and both result in solubilization of

CoQ10 in limonene. (Appx1203, Appx1206, Appx1417-1418.) The Board's judicial notice of the textbook definition of "dissolve" did not in any way change that thrust.

Second, Soft Gel had two opportunities to address this rejection before the Examiner and the Board. In the ACP, the Examiner addressed Soft Gel's false distinction between "dissolving" and "melting" by observing that "melting," "solubilizing" and "dissolving" are closely linked to one another. (Appx1203.) The Examiner further stated that "whether 'melting' is the same or different from 'dissolving' is of no import because the end result is the same: solubilization of coenzyme Q10 in lemon oil (d-limonene)." (Appx1206.) Soft Gel filed a response to the ACP, and the Examiner rejected Soft Gel's arguments and repeated her rejections in the RAN. (Appx1401-1410, Appx1417-1418.) Soft Gel had another opportunity to address the rejection in its appeal of the RAN, and the Board also rejected Soft Gel's false distinction between "melting" and "dissolving." Accordingly, Soft Gel had a fair opportunity to address the rejection, initially with the Examiner after the ACP, and then with the Board after the RAN.

Soft Gel fails to provide any explanation as to how the standard definition for "dissolve" was incorrect or how the Board's adoption of that definition changed the grounds for the rejection. A bald challenge to the Board's use of judicial notice without any explanation of why there may be doubt as to the noticed

facts is insufficient to reverse the Board's decision. *See In re Boon,* 439 F.2d at 728 ("[A] challenge to judicial notice by the board [must] contain adequate information or argument so that on its face it creates a reasonable doubt regarding the circumstances justifying the judicial notice.").

H. The Federal Court Judgment on an Unrelated Patent Has No Bearing On This Proceeding

Soft Gel's argument that the "Federal Court judgment is dispositive" as to whether the CoQ10 in Khan/Nazzal is melted and thereby solubilized, is without merit. First, Soft Gel did not raise this argument until its reply brief before the Board, and therefore the argument was waived. *See Ex Parte Borden*, 93 U.S.P.Q.2d 1473, 1474 (B.P.A.I. 2010) ("Any bases for asserting error, whether factual or legal, that are not raised in the principal brief are waived"). If the Court does consider this argument, the issues litigated in the federal court action were claim construction, infringement and validity of the Khan '786 patent. (Appx696-723.) The '072 patent, on the other hand, was not at issue in the federal court action, and the court did not in any way address the construction or validity of its claims. Thus, the issues litigated in the two proceedings are entirely different, and the federal court judgment on infringement of the Khan patent has no bearing on the issues here. *See In re Freeman*, 30 F.3d 1459, 1465 (Fed. Cir. 1994) (collateral estoppel applies only to an issue that is "identical to one decided in the first action" and "actually litigated in the first action.").

V. The Claims on Appeal Are Obvious in View of Motoyama, Khan, Nazzal and the Other Cited References

The Board affirmed the Examiner's rejections of claims 1-3, 5-10, 12-20 and 22-24 as obvious under 35 U.S.C. § 103(a) in view of Motoyama, Soft Gel's admission regarding Motoyama, Khan, and Nazzal, as evidenced by Fenaroli, Duetz, Mondello and IARC. (Appx26-30.) The Board's factual findings are supported by substantial evidence, and the Board correctly concluded based upon those factual findings that claim 1 would have been obvious. Soft Gel did not argue to the Board that the remaining claims are separately patentable. Accordingly, the Board's decision that claims 1-24 are unpatentable under § 103 should be affirmed.

A. Standard of Review on Obviousness

Obviousness is a question of law that is based upon underlying factual findings. The Board's legal conclusion of obviousness is reviewed *de novo*. *In re Klein*, 647 F.3d 1343, 1347 (Fed. Cir. 2011). The Board's factual findings underlying the determination of obviousness are reviewed for substantial evidence. *Id.* "A finding is supported by substantial evidence if a reasonable mind might accept the evidence to support the conclusion." *Husky Injection Molding Sys. Ltd. v. Athena Automation Ltd.*, – F.3d –, 120 U.S.P.Q.2d 1324, 1332, 2016 U.S. App. Lexis 17373 at *24 (Fed. Cir. 2016).

B. The Board's Factual Findings Are Supported by Substantial Evidence and the Conclusion that the Claims Would Have Been Obvious in View of Those Factual Findings Should Be Affirmed

The Board found that a preponderance of the evidence supported the Examiner's determination that claim 1 would have been obvious in view of Motoyama, Soft Gel's admissions regarding Motoyama, Khan, and Nazzal as evidenced by Fenaroli, Duetz, Mondello and IARC. (Appx26-30.) The Board made the following findings of fact supported by substantial evidence.

1. Motoyama Taught That CoQ10 Readily Dissolves in Carvone, Peppermint Oil or Spearmint Oil

Motoyama taught that CoQ10 "is highly soluble" in carvone, a monoterpene. (Appx180 at col. 1, Appx28 at FF12.) Motoyama further taught that carvone is a constituent of spearmint oil and peppermint oil, and that these oils "readily dissolve ubiquinone and thus are preferred as dispersion media." (*Id*.)Indeed, Soft Gel admitted that Motoyama taught solubilizing CoQ10 in l-carvone at an amount of up to 50% by weight (Appx2039-2040, Appx2044):

> [Motoyama] discloses that ubiquinone is solubilized in l-carvone, an essential oil derived from spearmint and peppermint oil, and d-carvone, derived from caraway seed oil. *See*, *e.g.* pp. 2, 4, and 5, Examples 1-5. Carvone is disclosed as particularly preferred for solubility of ubiquinone at a 50:50 weight ratio at room temperature.

(Appx2044.)

2. It Would Have Been Obvious to Substitute d-Limonene For the Carvone, Peppermint Oil or Spearmint Oil of Motoyama and Arrive at the Claimed Composition

Khan and Nazzal taught that lemon oil, peppermint oil and spearmint oil are about equally effective in reducing the melting point of CoQ10 to thereby solubilize the CoQ10 in the oil. (Appx495 at 6:27-40, Appx 483 at FIG. 4, Appx330 at Fig. 4.13, Appx1152 at ¶4, Appx28-29 at FF14.)

The '072 patent cites to the Kirk-Othmer Encyclopedia of Chemical Technology, 22:709-762 (1983) for its teaching that both carvone and limonene are monoterpenes, establishing that it was known in the prior art that these volatile components of essential oils are monoterpenes.[8] (Appx512 at 3:49-58 (FF12, FF15).) *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1362 (Fed. Cir. 2007) ("[a]dmissions in the specification regarding the prior art are binding on the patentee for the purposes of a later inquiry into obviousness"); *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1570 (Fed. Cir. 1988) ("A statement in a patent that something is in the prior art is binding on the applicant and patentee for determinations of anticipation and obviousness.").

[8]Soft Gel has not challenged and therefore acquiesced in this aspect of the Board's factual findings.

Fenaroli taught that lemon oil contains 90% by weight limonene, and that the form of limonene present in natural lemon oil is d-limonene.[9] (Appx1624.) These teachings were reinforced by Duetz ("d-limonene is the main constituent of orange and lemon peel oil (92 to 96%)," (Appx1987); Mondello (d-limonene (i.e., R(+) limonene) comprises 98.1% of lemon oil, (Appx1983 at Table 6); and IARC (d-limonene comprises 98-100% of the limonene in the *Rustaceae* family of citrus oils, which includes lemon. (Appx1624, Appx29 at FF15).

Nazzal taught that "[c]hemical components of essential oils such as limonene, menthone, and carvone can be evaluated for their potency in exerting a eutectic effect." (Appx456 at FF16.)

Based on the foregoing findings of fact, the Board correctly determined that it would have been obvious to a person of ordinary skill in the art to substitute d-limonene for the carvone, peppermint oil or spearmint oil of Motoyama and arrive at the claimed composition. Nazzal explicitly suggested that both limonene and carvone can be evaluated for their potency in solubilizing CoQ10. This teaching would have motivated a person of ordinary skill in the art to substitute d-limonene for the carvone, peppermint oil or spearmint oil of Motoyama. (Appx456.)

[9]Fenaroli was submitted and relied upon by Soft Gel during prosecution of the related '583 patent to overcome a rejection. (Appx2071, Appx2088.) Soft Gel's reliance on this evidence constitutes an admission as to the content of lemon oil. *In re Applied Materials*, 692 F.3d at 1297 (patentee's admissions regarding teachings of prior art binding on patentee); *In re Reuning*, 276 F. App'x 983, 986 (Fed. Cir. 2008) (same).

Indeed, Soft Gel's own expert in the federal court action, Dr. Dash, testified that it would have been "obvious to use or obvious to try lemon oil [in the composition described in Motoyama] based on . . . the level of ordinary skill in the art and the knowledge [of] a person of ordinary skill regarding the wide range of essential oils available." (Appx721.) In addition, Khan/Nazzal's teachings that lemon oil, peppermint oil and spearmint oil are about equally effective in reducing the melting point and thereby solubilizing the CoQ10, coupled with the prior art teachings that limonene and carvone are both monoterpenes and lemon oil is 90% d-limonene, would have provided the person of ordinary skill with a reasonable expectation of success in making the substitution.

Accordingly, there is substantial evidence in the record to support the Board's factual findings, as well as its conclusion that the composition recited in claim 1 of the '072 patent was obvious.

C. Substantial Evidence Supports the Finding That a Person of Ordinary Skill in the Art Would Have Been Motivated to Substitute d-Limonene for the Carvone, Peppermint Oil or Spearmint Oil of Motoyama With a Reasonable Expectation of Success

Soft Gel argues that the Board committed legal error because "one skilled in the art would not be motivated to substitute d-limonene into Motoyama's invention with a reasonable expectation of success." (Brief at 42.) Whether one skilled in the art would be motivated to combine or modify the prior art with a reasonable

expectation of success is a factual finding that is reviewed for substantial evidence. *Allied Erecting & Dismantling Co., Inc. v. Genesis Attachments, LLC*, 825 F.3d 1373, 1380 (Fed. Cir. 2016) ("We … review the PTAB's findings of a motivation to combine for substantial evidence."); *Belden*, 805 F.3d at 1073. "Obviousness does not require absolute predictability of success… all that is required is a reasonable expectation of success." *In re Kubin*, 561 F.3d 1351, 1360 (Fed. Cir. 2009).

As discussed *supra* at 47-50, (i) Motoyama taught that carvone is a component of spearmint oil and peppermint oil, and that carvone, spearmint oil and peppermint oil are effective in dissolving (i.e. solubilizing) CoQ10; (ii) Khan taught that lemon oil, spearmint oil and peppermint oil are about equally effective in solubilizing CoQ10; and (iii) Fenaroli and the other cited art taught that d-limonene is the main constituent of lemon oil. These teachings alone provide substantial evidence to support the Board's finding that one skilled in the art would have been motivated to substitute d-limonene for the carvone, spearmint oil or peppermint oil of Motoyama.

If that evidence were not enough, Nazzal specifically taught that limonene can be evaluated for its potency in melting and thereby solubilizing CoQ10, and Soft Gel's ***own expert*** testified that "substitution of lemon oil for other essential

oils is a predictable variation that would be known to one of ordinary skill." (Appx721.)

In the face of this substantial evidence supporting the Board's finding of a motivation to combine, Soft Gel resorts to speculation and conjecture. Soft Gel first argues that Khan's 2004 study on enantiomers of d-limonene somehow shows that Khan did not have an expectation that d-limonene would be effective in solubilizing CoQ10. (Brief at 42.) There is no evidence in the record regarding Khan's motivation or expectation in performing the subsequent studies with enantiomers of limonene, and Soft Gel's speculation on Khan's motivation or expectation is mere attorney argument. *In re Geisler*, 116 F.3d 1465, 1470 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness.").

Soft Gel's argument regarding Khan 2004 also fails because the data reported in Khan 2004 is consistent with the data reported in FIG. 4 of Khan, and there is nothing in Khan 2004 that suggests that Khan did not expect d-limonene to effectively solubilize CoQ10. Khan 2004 states that CoQ10 is soluble in d-limonene, with a solubility of about 571 mg/ml. (Appx658.) Khan 2004 shows that at the 90:10 CoQ10:d-limonene ratio, the only combination for which the melting point reduction was measured in Khan 2004, the melting point of CoQ10

was reduced from 51°C (its melting point outside the presence of d-limonene) to 49°C. (Appx659.) FIG. 4 of Khan indicates that the melting point reduction for a 90:10 combination of CoQ10 and lemon oil (which is 90% d-limonene) would be slight and in the range reported by Khan 2004. (Appx483 at FIG. 4, Appx1156-1157 at ¶14.) Accordingly, Khan 2004 further supports the conclusion that d-limonene can effectively solubilize CoQ10.

Soft Gel argues that there was no motivation to substitute d-limonene for carvone because the "basis" for Motoyama's selection of peppermint oil and spearmint oil is that those oils contain carvone, whereas Khan selected those oils and lemon oil due to their volatility. Soft Gel further argues that (i) Motoyama and Khan do not specifically mention limonene; and (ii) Nazzal "contains only a limited disclosure of whether limonene should be investigated." (Brief at 45-46.)

Soft Gel again relies entirely on attorney argument, and does not point to any evidence in the record that one skilled in the art would not have had a reasonable expectation of success based upon the results and teachings of Motoyama, Khan, and Nazzal, and the evidence regarding the d-limonene content of lemon oil. *See In re Geisler*, 116 F.3d at 1470 (attorney argument insufficient to overcome *prima facie* case of obviousness). Indeed, the evidence in the record proves the opposite. Soft Gel's own expert testified that "substitution of lemon oil for other essential oils is a predictable variation that would be known to one of

ordinary skill." (Appx721.) Nazzal explicitly taught that limonene can be evaluated for its potency in melting and thereby solubilizing CoQ10. (Appx456.) There is substantial evidence that d-limonene is the main constituent of lemon oil, and the only isomer of limonene that occurs in nature. *Supra* at 28-31. Accordingly, substantial evidence supports the Board's conclusion that one skilled in the art would have been motivated to substitute d-limonene for the carvone, peppermint oil or spearmint oil in Motoyama with a reasonable expectation of success, and the Board's decision in this regard should be affirmed.

D. There is No Dispute that the Only Form of Limonene that Occurs in Nature is d-Limonene, and Therefore the Board's Statement That Nazzal Suggests Testing of d-Limonene is Supported by Substantial Evidence

Soft Gel argues that the Board erred by stating that Nazzal "explicitly suggested d-limonene for future studies." (Appx31-32.) As the Board stated in its findings of fact, d-limonene is the main constituent of lemon oil (Appx29 at FF15), and Nazzal recommended that limonene can be evaluated to determine its "potency" in melting and thereby solubilizing CoQ10. (Appx29 at FF16.) It was reasonable for the Board to infer from these factual findings that Nazzal's suggestion to evaluate limonene referred to d-limonene.

Soft Gel admitted during prosecution of the '583 patent that lemon oil contains approximately 90% d-limonene and that citrus oils (e.g. lemon oil) contain only d-limonene. (Appx2071, Appx2088.) Specifically, Soft Gel argued

in support of patentability of the claims of the '583 patent that "lemon oil contains d-limonene" and distinguished "d-limonene" from "l-limonene" which "is not used as a solvent but rather is used as a botanical insecticide." (Appx2073.) Soft Gel also submitted evidence establishing that limonene is found in lemon oil, and that biological sources of lemon oil produce only one enantiomer, d-limonene. (Appx2081-2082.) Finally, Soft Gel submitted information from a NIH web site on lemon oil, and cited to this evidence in its office action response. (Appx2088.) Soft Gel included a pinpoint cite to the section of the NIH web site that states that lemon oil "contains approx. 90% limonene." (Appx2071.) Accordingly, during prosecution, Soft Gel submitted and relied upon evidence establishing that lemon oil contains approximately 90% limonene, and that the enantiomer that occurs naturally in lemon oil is d-limonene. *In re Applied Materials*, 692 F.3d at 1297 (patentee's admissions regarding teachings of prior art binding on patentee); *In re Reuning*, 276 F. App'x at 986.

In addition to the evidence submitted by Soft Gel, Jarrow submitted substantial evidence that lemon oil contains a high percentage of d-limonene. *See supra* at 28-31. Accordingly, there is substantial evidence in the record to support the Board's finding that a person of ordinary skill in the art would have understood Nazzal to teach that d-limonene can be evaluated for its potency in melting and thereby solubilizing CoQ10.

Soft Gel points to the Board's decision on rehearing in a related case, where the Board indicated that it erred in stating that "Nazzal expressly suggested evaluating d-limonene." (Appx3521.) While Nazzal's statement did not expressly refer to d-limonene, it was reasonable for the Board to infer that Nazzal was referring to d-limonene, the only enantiomer that occurs in nature. In any event, the Board went on to find that, in view of the evidence cited *supra* at 28-31, "it would have been obvious to have evaluated the d-form [of limonene] for its potency in lowering the melting temperature of Q10 and in Motoyama's method." (Appx3521-3522.) The Board further found that this clarification did not change its decision on obviousness. (Appx3523.) Accordingly, if this Court were to agree that the Board made a misstatement regarding Nazzal's statement, it should not change the result and the Board's decision nevertheless should be affirmed. *South Ala. Med. Sci. Found. v. Gnosis S.P.A.*, 808 F.3d 823, 828 (Fed. Cir. 2015) (upholding PTAB's obviousness determination despite harmless error regarding evaluation of one secondary consideration of obviousness, when all other obviousness criteria supported the PTAB's determination); *Watts*, 354 F.3d at 1369 (harmless error doctrine applies "when a mistake of the administrative body is one that clearly had no bearing on the procedure used or the substance of the decision reached").

E. The Factual Finding That d-Limonene is the Main Constituent of Lemon Oil Is Supported by Substantial Evidence

Soft Gel argues that the Board's factual finding that d-limonene is "the main component of lemon oil" is not supported by substantial evidence. (Brief at 46-47.) Soft Gel's argument falls flat because all of the evidence of record – including the evidence submitted by Soft Gel – supports the Board's finding.

As discussed *supra* at 28-29, Soft Gel submitted to the PTO during prosecution of the related '583 patent the Fenaroli and Wikipedia references to argue that their teachings with respect to d-limonene support the patentability of the claims. (Appx2071, Appx2081-2082, Appx2088.) Having submitted these references to argue that their teachings on d-limonene support patentability, Soft Gel cannot now argue that their teachings on d-limonene are incorrect. *In re Applied Materials*, 692 F.3d at 1297 (patentee's admissions regarding teachings of prior art binding on patentee); *In re Reuning*, 276 F. App'x at 986. Jarrow submitted the Duetz, Mondello and IARC references with its reexamination request, which provide further evidence that lemon oil contains 90% or more d-limonene. (Appx1106, Appx1983 at Table 6, Appx1987.) Accordingly, the Board's finding that d-limonene is the main constituent of lemon oil is supported by substantial evidence.

During prosecution of the reexamination, Soft Gel tried to rebut the evidence that it had previously submitted, and the additional evidence submitted by Jarrow,

by submitting two articles, Lota and Steuer. (Appx1253-1268.) Soft Gel argues that the Board's factual finding should be reversed because of the nineteen tests of various species and cultivars of lemon oil conducted by Lota, one revealed 38.1% d-limonene. (Appx1260.) Even in that sample, however, d-limonene was the largest constituent, which caused Lota to state that "[l]imonene was always the main constituent (38.1-95.8%) of all oils." (Appx1262.) Similarly, Steuer states that limonene is the "main component of citrus peel oils…," and reports tests showing that lemon oil contains 68% limonene. (Appx1253, Appx1255 at Table 1.) Accordingly, the Board's finding that d-limonene is the main constituent of lemon oil is supported by substantial evidence.

Soft Gel argues that the Board's decision on the request for rehearing in a related case clarifying its finding to state that d-limonene is "one of the main constituents in lemon oil" warrants reversal in this case. (Brief at 47.) First, Jarrow disagrees that the Board needed to clarify its finding. As discussed *supra* at 28-31, all of the record evidence establishes that d-limonene is the main constituent of lemon oil, and therefore the Board's factual finding is supported by substantial evidence and should not be disturbed. Second, in the related case, the Board found that its minor clarification of the finding did not change its obviousness determination. (Appx3523.) Accordingly, if the Court were to adopt such a clarification, which Jarrow submits would not be proper, the obviousness decision

nevertheless should be affirmed. *South Ala. Med. Sci. Found.*, 808 F.3d at 828; *In re Watts*, 354 F.3d at 1369.

F. The Rejection of Claims 4, 11, 12, 21 and 22 as Obvious Should Be Affirmed Because Soft Gel Has Not Made Any Argument That the Additional Limitations of These Claims Distinguish Over the Cited References

The Board affirmed the rejection of dependent claims 4, 11 and 21 as obvious in view of Nazzal and Steele, and dependent claims 12 and 22 as obvious in view of Nazzal and Motoyama. (Appx27-28.) These claims depend from independent claims 1 and 15. The Board found that Nazzal anticipates claims 1 and 15, and therefore disclose all of the limitations of the independent claims. (Appx24.) Soft Gel challenged the obviousness rejection of claims 4, 11, 12, 21 and 22 by incorporating its argument that Nazzal does not anticipate claim 1, and arguing that Steele and Motoyama do not cure the "deficiencies" in Nazzal regarding anticipation. (Brief at 47, Appx27-28.) As discussed *supra* at Section IV, the Board correctly affirmed the rejection of claim 1 as anticipated. Because Soft Gel has made no additional arguments regarding the patentability of claims 4, 11, 12, 21 and 22 , the rejection of these claims as obvious should be affirmed. *Affinity Labs of Tex., LLC v. Amazon.com, Inc.*, – F.3d –, 2016 U.S. App. Lexis 17370 at *4 n.2, 120 U.S.P.Q.2d 1210, 1211 n.2 (Fed. Cir. 2016) ("Because [patent owner] has failed to present 'any meaningful argument for the distinctive

significance of any claim limitations' other than those in claim 14, we treat claim 14 as representative of all of the claims for purposes of this appeal.").

The Examiner also rejected dependent claims 4, 11 and 21 as obvious in view of Khan and Steele, and dependent claims 12 and 22 as obvious in view of Khan and Motoyama. (Appx4.) As discussed *supra* at Section III, the Board did not address these rejections and therefore the rejections are presumed to have been affirmed by the Board. Soft Gel concedes that the disclosures of Khan and Nazzal are the same. (Appx980.) Accordingly, the rejections of claims 4, 11, 12, 21 and 22 as obvious in view of Khan, Steele and Motoyama should be affirmed for the same reasons as the corresponding rejections based on Nazzal.

The Board also affirmed the rejection of dependent claims 4, 11 and 21 as obvious in view of Khan, Nazzal, Motoyama, Patent Owner's admission on Motoyama, and Steele as evidenced by Fenaroli, Duetz, Mondello and IARC, and the rejection of dependent claims 12 and 22 as obvious in view of Khan, Nazzal, Motoyama, Patent Owner's admission on Motoyama, and Davidson as evidenced by Fenaroli, Duetz, Mondello and IARC. (Appx32-33.) Soft Gel does not challenge these rejections in its brief. Accordingly, these rejections should be affirmed for the reasons stated by the Board.

CONCLUSION

For the foregoing reasons, it is respectfully submitted that the Court affirm the rejections of claims 1-2, 6-10, 14-20 and 24 as anticipated, and claims 1-24 as obvious.

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CERTIFICATE OF SERVICE

I hereby certify, that on November 2, 2016, a true and correct copy of the Corrected Brief of Appellee Jarrow Formulas, Inc. was caused to be served on the below-listed counsel by CM/ECF and electronic mail (by agreement of counsel):

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CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B). The brief contains 13,373 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). The brief has been prepared in a proportionally spaced typeface using MS Word in a 14 point Times New Roman font.

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